Commonwealth of Massachusetts Center for Health Information & Analysis (CHIA) Non-Government Application for MA APCD Limited Data Set

This form is required by all Applicants, except Government Agencies as defined in 957 CMR 5.02. All Applicants must also complete the Data Management Plan, attached to this Application. The Application and the Data Management Plan must be signed by an authorized signatory of the organization. This Application and the Data Management Plan will be used by CHIA to determine if your organization may receive CHIA data. Please be sure the documents are completed fully and accurately. You may wish to consult the Evaluation Guide that CHIA will use to review your documents. Prior to receiving CHIA Data, the organization must execute the Data Use Agreement. You may wish to review that document as you complete these forms. This application should be completed by the Primary Investigator, and must be signed by a party with authority to bind the organization seeking CHIA Data for the purposes described herein.

<u>NOTE</u>: In order for your Application to be processed, you must submit the required application fee. Please consult the fee schedules for MA APCD data for the appropriate fee amount. A <u>remittance</u> form with instructions for submitting the application fee is available on the CHIA website.

All attachments must be uploaded to IRBNet with your Application. All applications documents can be found on the <u>CHIA website</u> in Word and/or PDF format.

I. GENERAL INFORMATION

APPLICANT INFORMATION	
Applicant Name:	Cecilia Lee, MD MS
(Primary Investigator)	
Title:	Assistant Professor
IRBNet #	936628-1
Organization:	University of Washington, Seattle
Project Title:	Retrospective Analysis of Ocular Data from the Massachusetts Center for Health Information Analysis (CHIA) Database (same as previous title noted on the data manamgement plan).
Mailing Address:	HMC 359608, 325 9 th Ave, Seattle, WA 98104
Telephone Number:	206-685-4705
Email Address:	Leecs2@uw.edu
Names of Co-Investigators:	Aaron Lee, MD
Email Addresses of Co-Investigators:	leeay@uw.edu
Original Data Applicant Submission Date:	08-03-2016
Dates Data Application Revised:	09-22-2016 07-10-2019
Project Objectives (240 character limit):	To evaluate the epidemiology and risk factors of major sight-threatening ophthalmic conditions such as diabetic retinopathy, age-related macular degeneration, glaucoma, cataract, uveitis, corneal ulcers, ocular trauma and ocular melanoma and to determine the factors associated with the access, outcome and delivery of ophthalmic care for these

	conditions in the state of MA using MA All-payers Claims CHIA Database.
Project Research Questions (if applicable) or Business Use Case(s):	Are there associations between the severity of diabetic retinopathy and age-related macular degeneration?
	2. Are patients who had vitrectomy surgery for proliferative diabetic retinopathy at increased risk for the following events: Myocardial infarction, dialysis, stroke, hospitalization, and mortality in a health care setting?
	3. Are patients who had pan-retinal photocoagulation for proliferative diabetic retinopathy at increased risk for the following events: Myocardial infarction, dialysis, stroke, hospitalization, and mortality in a health care setting?
	4. Are patients who had intravitreal vascular- endothelial growth factor inhibitor for diabetic macular edema at increased risk for the following events: Myocardial infarction, dialysis, stroke, hospitalization, and mortality in a health care setting?
	5. Does the epidemiology of major sight- threatening ophthalmic conditions differ by sociodemographic, geospatial, seasonal factors?
	6. How does the access, delivery, and outcome of ophthalmic care differ between major sight-threatening ophthalmic conditions?

II. PUBLIC INTERST & PROJECT SUMMARY

1. Briefly explain why completing your project is in the public interest.

All our study questions have direct public health implications since we are interested in finding out whether diabetic retinopathy is associated with other morbidity and mortality in a health care setting. No prospective clinical trial will be able to find an answer to these questions since this will require a large sample size with long follow up.

In addition to studying the risk factors for diabetic retinopathy and its associations with other ocular or systemic conditions, we propose to evaluate similar risks for major sight-threatening ophthalmic conditions. Major causes of global blindness include diabetic retinopathy, age-related macular degeneration, glaucoma, cataract, corneal ulcers, uveitis, ocular trauma and ocular melanoma according to the World Health Organization and American Academy of

Ophthalmology statistics. Using the MA APCD (CHIA data), we will establish the epidemiology and risk factors for these major sight-threatening ophthalmic conditions and determine the factors associated with the access and delivery of ophthalmic care. At the completion of the proposed studies, we will have a better understanding of current epidemiology and risk factors of ophthalmic diseases, real-world delivery of ophthalmic care, and factors related to the access and outcomes of ophthalmic diseases. These results will not only improve the understanding of ophthalmic pathologies in the scientific community, they will have the potential to influence current standard of care, public health policies, and/or resource allocations. Furthermore, we plan to publish all our findings in peer-reviewed journals, thus any important results will be shared with the public.

2.	Has an Institutional Review Board (IRB) reviewed your project?
	oximes Yes, a copy of the approval letter and protocol must be attached to this Application
	\square No, this project is not human subject research and does not require IRB review.

3. If your project has not been reviewed by an IRB, please **attach** a brief (1-2 page) description of your project including the methodology, objectives, and research questions.

III. DATA FILES REQUESTED

1. Please indicate the MA APCD databases from which you seek data, the year(s) of data requested, and your justification for requesting <u>each</u> file. Please refer to the <u>MA APCD Release 5.0 Data Specifications</u> for details of the file contents.

MA ALL-PAYER CLAIMS DATABASE FILES	Year(s) Of Data Requested Current Yrs. Available ☑ 2011 ☑ 2012 ☑ 2013 ☑ 2014 ☑ 2015
	Please describe how your research objectives require Medical Claims data:
	We are doing medical research regarding treatment outcomes, medical claims is necessary to perform the work. We are requesting Data from the currently available years: 2011-2015.
	For the renewal, we are asking for versions 6.0 and 7.0 to obtain the data from 2012-2017
☑ Pharmacy Claims	Please describe how your research objectives require Pharmacy Claims data:
	A significant portion of patients with diabetic retinopathy and age-related macular degeneration receives vascular endothelial growth factor inhibitor. There are other medications such as statin that has been associated with uveitis and diabetic retinopathy. We propose to analyze associations between systemic medications and sight-threatening ophthalmig conditions. In addition, we will need to identify the medications that were used for treatment of ophthalmic conditions to be able to determine their severities and the clinical outcomes.
☐ Dental Claims	Please describe how your research objectives require Dental Claims data:

☐ Member Eligibility	Please describe how your research objecti	Please describe how your research objectives require Member Eligibility data:					
Wember Enginity	l lease describe now your research object.	ves regame member 2.18.2, data.					
⊠ Provider	Please describe how your research objecti	ves require Provider data:					
	One of the important goals of our stud	ly is to determine the factors associated with					
		er types are an important variable in this					
	study. We are requesting Data on all a	vailable providers.					
☐ Product	Please describe how your research objecti	ves require Product data:					
IV. GEOGRAPHIC DETAIL	· Contanto	Famuel and with Edinitain and CIIIA will					
		For releases with 5 digit zip code, CHIA will					
apply a substance abuse filter (which will remove all claims that include a	substance abase alagnosis.					
☐ 3 Digit Zip Code (MA) (star	ndard) × 5 Digit Zir	o Code (MA)***					
	on for requesting 5 digit zip code. Refer to						
	, , ,	* **					
		the patients' clinical outcome is access to					
care and we will use the dista	ance information from their usual hospita	als or physicians.					
V. DATE DETAIL							
	the following options for dates:						
Chamber (Cod 64)							
☐ Year (YYYY) (Standard)	☐ Month (YYYYMM) *** ☐ Day (YYYYMMDD) ***						
		[for selected data elements only]					
		Day. Refer to specifics in your methodology:					
proprieta de la companya del companya de la companya del companya de la companya del la companya de la companya		ng detailed date information will help us analyze					
Language and the contract of t	een the eye surgery and additional outcomes o						
Also time dependent survival an	ialysis regarding various outcomes will be perf	ormed using cox regression (which will require					
dates).							

VI. NATIONAL PROVIDER IDENTIFIER (NPI)

Please choose <u>one</u> of the following options for National Provider Identifier(s):

	pted National Provider Identifier(s) (standard)
specifics unencry determin	quested please, provide justification for requesting unencrypted National Provider Identifier(s). Refer to in your methodology: In order to associate outcomes with provider type/level of specialty we plan to link oted NPI with CMS NPI Registry data and/or AMA physician master file date. This will allow us, for example, to ne if health outcomes vary when patients seek care at smaller community hospitals compared to large hospitals such as Massachusetts Eye and Ear.
1.41	
	ICAID DATA
*****	icate here whether you are seeking Medicaid Data: Yes
	No
directly co above, ple data will b	w (42 USC 1396a(a)7) restricts the use of individually identifiable data of Medicaid recipients to uses that are innected to the administration of the Medicaid program. If you are requesting Medicaid data from Level 2 or case describe, in the space below, why your use of the data meets this requirement. Requests for Medicaid be forwarded to MassHealth for a determination as to whether the proposed use of the data is directly to the administration of the Medicaid program.
VIII. DATA	A LINKAGE AND FURTHER DATA ABSTRACTION
	a linkage involves combining CHIA Data with other databases to create one extensive database for analysis. ge is typically used to link multiple events or characteristics that refer to a single person in CHIA Data within ase.
	ntend to link or merge CHIA Data to other datasets? Yes
	No linkage or merger with any other database will occur
2 If yes ni	ease indicate below the types of database to which CHIA Data be linked. [Check all that apply]
	Individual Patient Level Data (e.g. disease registries, death data)
	Individual Provider Level Data (e.g., American Medical Association Physician Masterfile)
	Individual Facility Level Data level (e.g., American Hospital Association data)
	Aggregate Data (e.g., Census data) Other (please describe):
ا	Other (piease describe).
3. If yes, de	escribe the data base(s) to which the CHIA Data will be linked, which CHIA data elements will be linked; and

the purpose for the linkage(s):

Driving distance to provider will be extrapolated with ZIP Code GPS coordinate using Open Street Map

Unencrypted NPI will be linked with CMS NPI data and/or AMA physician master file date to determine provider level of specialty/expertise.

Open-source meteorological and satellite data such as from NASA will be linked by the zipcode and time.

4. If yes, for each proposed linkage above, please describe your method or selected algorithm (e.g., deterministic or probabilistic) for linking each dataset. If you intend to develop a unique algorithm, please describe how it will link each dataset.

Driving distance - Probabilistic

Linkage of unencrypted NPI to CMS NPI data -Deterministic

Linkage of meteorological and satellite data- Determininistic

5. If yes, please identify the specific steps you will take to prevent the identification of individual patients in the linked dataset.

Driving distance - Open Street map travel distance calculations are based on census ZIP code area centroids which is fuzzy matching routine rather than exact matching to patient address and analysis of distance will be aggregated.

All linked and merged data will be aggregated and not reported at patient level and will utilize cell suppression.

XI. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from such CHIA Data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting. All publication of CHIA Data must comply with CHIA's cell size suppression policy, as set forth in the Data Use Agreement. Please explain how you will ensure that any publications will not display a cell less than 11, and no percentages or other mathematical formulas will be used if they result in the display of a cell less than 11.

We plan to publish our findings in peer-reviewed journals and during appropriate research conferences.

2. Do you anticipate that the results of your analysis will be published and/or publically available to any interested party? Please describe how an interested party will obtain your analysis and, if applicable, the amount of the fee, that the third party must pay.

The results will be available through our publications.

B. Will you use CHIA Data for consulting purposes? ☐ Yes ☑ No
. Will you be selling standard report products using CHIA Data? ☐ Yes ☑ No
. Will you be selling a software product using CHIA Data? ☐ Yes ☑ No
. Will you be reselling CHIA Data in any format? ☐ Yes ☑ No
yes, in what format will you be reselling CHIA Data (e.g., as a standalone product, incorporated with a software roduct, with a subscription, etc.)?
. If you have answered "yes" to questions 4, 5 or 6, please describe the types of products, services or studies.
. If you have answered "yes" to questions 4, 5, or 6, what is the fee you will charge for such products, services or cudies?

X. APPLICANT QUALIFICATIONS

1. Describe your qualifications (and the qualifications of your co-investigators) to perform the research described.

Aaron Lee MD, MSCI and Cecilia Lee MD, MS are both clinician-scientists and have extensive experience in the outcome research using large datasets. Drs. Lee have published more than 20 peer-reviewed publications using similar datasets in ophthalmology. Dr. Aaron Lee has a Master of Science in Clinical Investigation and is considered a leading expert in machine learning applications in ophthalmology. Dr. C. Lee has a Masters of Science in epidemiology and is an expert in Big Data related outcome research. Both Drs. Lee are currently funded by NIH as K23 awardees to pursue clinical research.

	Lee (PI), A. Lee(co-investigator), L. Ding (statistician), Ian Luttrell (research cordinator) and has the clinical and statistical expertise to perform the
2. Attach résumés or curricula vita will not be posted on the internet	ae of the Applicant/principal investigator, and co-investigators. (These attachments
XI. USE OF AGENTS AND/OR CO	NTRACTORS
	cation, the Organization assumes all responsibility for the use, security and its agents, including but not limited to contractors.
Third-Party Vendors. Provide the	following information for all agents and contractors who will work with the CHIA Data.
Company Name:	
Contact Person:	
Title:	
Address:	
Telephone Number:	
E-mail Address:	
Organization Website:	× × ×
database? Yes, a separate Data M No Describe the tasks and products	anagement Plan <u>must</u> be completed by each agent who will store CHIA Data assigned to this agent for this project; their qualifications for completing the tasks; of the agent, including how the Organization will ensure the security of the CHIA Data
☒ Researcher☐ Others (Single Use)☐ Others (Multiple Use)	or MA APCD Data and select from the following options:
Are you requesting a fee waiver?	

If yes, please refer to the <u>Application Fee Remittance Form</u> and submit a letter stating the basis for your request (if required). Please refer to the <u>fee schedule</u> for qualifications for receiving a fee waiver. If you are requesting a waiver

☐ Yes ⊠ No

based on the financial hardship provision, please provide documentation of your financial situation. Please note that non-profit status alone isn't sufficient to qualify for a fee waiver.

By submitting this Application, the Data Applicant attests that it is aware of its data use, privacy and security obligations imposed by state and federal law *and* is compliant with such use, privacy and security standards. The Data Applicant further agrees and understands that it is solely responsible for any breaches or unauthorized access, disclosure or use of any CHIA Data provided in connection with an approved Application, including, but not limited to, any breach or unauthorized access, disclosure or use by its agents.

Applicants requesting data from CHIA will be provided with data following the execution of a Data Use Agreement that requires the Data Applicant to adhere to processes and procedures aimed at preventing unauthorized access, disclosure or use of data.

By my signature below, I attest to: (1) the accuracy of the information provided herein; (2) that the requested data is the minimum necessary to accomplish the purposes described herein; (3) the Data Applicant will meet the data privacy and security requirements describe in this Application and supporting documents, and will ensure that any third party with access to the data meets the data use, privacy and security requirements; and (4) my authority to bind the organization seeking CHIA Data for the purposes described herein.

Signature: (Authorized Agent)	Muslene
Printed Name :	Dr. Russell Van Gelder
Title:	Professor and Chair
Signature: (Applicant/Primary Investigator)	and the second s
Name:	Dr. Cegolia Lee
Title:	Assistant Professor
Original Data Request Submission Date:	08-03-2106
Dates Data Request Revised:	09-22-2016 07-10-2019

Attachments. Please indicate below which documents have been attached to the Application and uploaded to IRBNet:

- ☑ 1. IRB approval letter or summary of project (if applicable)
- ☑ 2. Resumes of Applicant and co-investigators
- ☑ 3. Data Management Plan (for each institution that will store CHIA Data)

$m{W}$ university of Washington

PAPER APPLICATION: Continuing Review (Status Report), Renew or Close

Version 5.6

Human Subjects Division Box 359470 Seattle, WA 98195-9470 Phone: 206-543-0098 Fax: 206-543-9218

For instructions on how to complete this form, see the <u>last page</u>.

Use this form ONLY when a paper-based Status Report is being submitted. Do not use this form with the web-based *Zipline* application system or for paper-based applications that are being converted to a *Zipline* application.

For HS	SD Office Use Only	Na literatura de care	Date Received:	
[] Master Copy	[1] Approved		Human Subjects Division	
[] IRB Working Copy	[] Disapproved		JUN 2 0 2019	
[] Researcher Copy	[] Withdrawn	* 1	0011 2 0 2010	
[] Full IRB Review Required				
M Expedited Review			DORA CRR#	
Approval period from: 7 - 28	3-19	To: 7-27-	20	
Date of IRB action: 7-2-19		Printed name: Ariana Chantee		
IRB Chair or Designee Signature:	Ariano C	hantie		

lavoigas BRI	Research St	udy Informat	tion		roy ex entitle * \
Submission Reason [X] RENEW IRB application		[] CLOSE IRB application			
Expiration date of IRB ap	proval		7/27/2019		,
IRB Application #	52359		IRB Commit	Committee E/D	
IRB Application Title	Retrospective Analysis of Oc Information Analysis (CHIA) I		om the Massa	chusetts	Center for Health
Lead Researcher Name	Cecilia Lee, MD	Contac	t Name	Ian	Luttrell
Position and/or academic appointment	Assistant Professor		Position and/or academic appointment		dinator
Department/Division	Ophthalmology	Departm	ent/Division	Opht	halmology
Phone #	- 2	Phone #		206-	520-8305
Fax#		Fax#		20-5	20-8399
Campus Box #	359608	Campus	Box#	3596	808
Street address, if applicable		Street ad applicabl			
Email	Leecs2@uw.edu	Email		luttri@uw.edu	
[] Person completing this form	is the same as the Lead Researcher	[X] Perso	on completing this	form is the	e same as the Contact
Name of Person Completing This Form (If not Lead Researcher or Contact):			Email:		Phone:
(if blank,	Name and Mailing Address for correspondence will be directed to cont				et person)
Name:	Campus Box#:	Other addre	ess if not at UW	:	
			7,		

A. Research Activity Status

PAPER APPLICATION: Continuing Review (Status Report), Renew or Close

Version 5.6

- Unexpected,
- Related or possibly related to participation in the research, AND
- Suggests that the research places (or could have placed) subjects or others at a greater risk of harm than was previously known or recognized. This includes physical, psychological, economic, or social harm.

Examples include: severe dizziness when the consent form listed mild dizziness as a risk, and loss of identifiable research data.

NOTE: Events which meet the definition of an unanticipated problem must be submitted using the REPORT: Problems form within 10 business days of discovery. If you have not yet submitted a Problem Report for any such events, do so now. (See SOP Reporting by Researchers.)

1. Describe each unanticipated problem that occurred in the last approval period in the table below (if none, write N/A):

Description of event	Problem Report/Modification #:
N/A	

2.	Provide a description of any complaints received in the last approval period (if none, v	write N/A):
	N/A	

3.	Does this study have a DSMB (Data and Safety Monitoring Board) or other safety monitor?
	[] Yes [X] No

If YES: a.) If you have not already, submit a modification to add any DSMB reports received during the last study approval period.

- b.) Append all DSMB reports received during the last approval period to this status report.
- c.) Explain any concerns that the DSMB had about the study here:

4.	Are you aware of any new information from the events described in this section or any other source
	(e.g. publications) that suggest the research places subjects at greater risk than described in your
	initial IRB application or subsequent modifications?
	[]Yes [X] No

a. If YES, provide an explanation of the new information and its impact on the risk assessment here:

E. Financial Conflict of Interest:

- Confirm by checking the box that the principal investigator on this application has ensured that any investigators (as defined by UW policy GIM 10) added to this research are aware of policy GIM 10 and their responsibility for complying with its relevant requirements.
 [X] Confirmed
- 2. Has a new financial conflict of interest developed for any investigator since the last IRB approval of this study (that is, since the last Status Report or the approval of the initial application, whichever is most recent)? [X] Yes [] No
 - a. If YES: Has it been disclosed to the University? (Since August 24, 2012, all disclosures are

Project Title:

Retrospective Analysis of Ocular Data from the Massachusetts's Center for Health Informatic Analysis (CHIA) Database

Specific Aims:

Diabetic retinopathy is the leading cause of blindness in the adult population worldwide. Although the association of diabetic retinopathy and other systemic comorbidities has been studied in epidemiology studies, they have been of relatively small sample size or a specific cohort such as a geographically confined population or of one insurance carrier. Thus, no study has been able to establish the relationship between the severity of diabetic retinopathy and systemic comorbidities or mortality in a health care setting at a large scale as proposed in our study.

Center for Health Information and Analysis (CHIA) Massachusetts (MA) data set is an extensive database of all MA payers, therefore can provide the patient-level data of the population at large for a large epidemiological study. By using extensive claims data, we are able to define patients who had a diagnosis of diabetic retinopathy of varying severity and associated procedures and surgeries, which may give us an enriched patient-level clinical data. Using this data, we propose to: 1) establish the prevalence of diabetic retinopathy of each severity in MA cohort, 2) determine the association between the severity of diabetic retinopathy and agerelated macular degeneration, another leading cause of blindness in patients above 60 years old; 3) determine the association between proliferative diabetic retinopathy and significant morbidities and mortality in a health care setting(defined as myocardial infarction, dialysis, stroke, and hospitalization); and 4) the association between diabetic macular edema undergoing treatment with significant morbidities and mortality in a health care setting. At the end of our studies, we will have established the association between the severity of diabetic retinopathy and systemic morbidities and mortality in a health care setting, which has significant public health implications in determining public and healthcare personnel education, allocation of resources, and directions of future health policies.

Specific Aim 1. To determine the prevalence of diabetic retinopathy of each severity in MA population.

We will perform descriptive analyses on the prevalence of diabetic retinopathy and associated procedures or surgeries (intravitreal injections, panretinal photocoagulation, pars plana vitrectomy, etc). We hypothesize that the prevalence of diabetic retinopathy will be high but differ between populations of varying geographic locations, and insurance status.

Specific Aim 2. To evaluate the access of care for patients with diabetic retinopathy in MA population.

We will assess how much patients have to travel for their eye care and determine whether distance is associated with higher severity of diabetic retinopathy, systemic morbidities and mortality in a health care setting. Using Geographic Information Systems, we will map the zip codes to a GPS coordinate and use Open Street Map data to assess driving distance to the eye care provider. We hypothesize that limited access of care will be associated with increased severity of diabetic retinopathy requiring more surgeries and higher overall mortality.

Specific Aim 3. To determine the association between diabetic retinopathy and macular degeneration.

We will use multivariate logistic regression to investigate the association between diabetic retinopathy and macular degeneration. We hypothesize that the presence of diabetic retinopathy will be inversely related to macular degeneration.

Specific Aim 4. To determine the association between diabetic retinopathy and significant morbidities and mortality in a health care setting.

We will analyze the risk of significant morbidities (defined as myocardial infarction, dialysis, stroke, hospitalization) and overall-mortality in patients with diabetic retinopathy using survival analyses. Time to development of significant morbidities in patients with diabetic retinopathy—1) patients undergoing pars plana vitrectomy, 2) patients undergoing panretinal photocoagulation, will be compared to those without diabetic retinopathy, controlling for age, gender, and other systemic risk factors. We hypothesize that the presence of diabetic retinopathy, proliferative type in particular, will be associated with increased morbidities and mortality in a health care setting.

Specific Aim 5. To determine the association between macular edema and significant morbidities and overall mortality.

We will analyze the risk of significant morbidities (defined as myocardial infarction, dialysis, stroke, hospitalization) and mortality in a health care setting in patients with diabetic macular edema undergoing intravitreal injection of anti-vascular endothelial growth factor using survival analyses. Time to development of significant morbidities in patients with diabetic macular edema undergoing active treatments will be compared to those without diabetic retinopathy, controlling for age, gender, and other systemic risk factors. We hypothesize that diabetic macular edema requiring treatments will be associated with increased morbidities and mortality in a health care setting.

Revision 07.10.2019

Our previous proposal focused in diabetic retinopathy to determine its epidemiology, risk factors, and associations with other ocular or systemic conditions. To allow us to understand how the care of diabetic retinopathy truly differs from other ophthalmic conditions, we wish to expand our research questions to major sight threatening conditions such as diabetic retinopathy, age-related macular degeneration, glaucoma, cataract, uveitis and ocular melanoma. The following is the revised rationale and proposed specific aims:

Globally, 1.8 billion people live with visual impairment. Leading causes of blindness include uncorrected refractive error, cataract, age-related macular degeneration, diabetic retinopathy, glaucoma, and corneal opacity. [1,2] Similarly, top causes of blindness in the United States include age-related macular degeneration, diabetic retinopathy, glaucoma, cataract, uveitis, and ocular trauma. [1][2] Understanding the epidemiology of blinding conditions and determining their risk factors is a key step towards improving our knowledge of these sight threatening pathologies and creating better strategies to optimize our healthcare delivery. Traditional epidemiology studies such as the National Health and Nutrition Examination Survey (NHANES) or the Global Burden of Disease (GBD) are excellent sources of understanding the prevalence and incidence of ocular disease burden, but they require significant funding and manpower.

The American Reinvestment and Recovery Act created the Massachusetts (MA) All Payers-Claims Database (APCD) program to enable detailed, comparative financial and health research. Longitudinal claims data paid for every state resident including all public and private payers are included in MA APCD. Approximately 7 years of longitudinal data exist and will continue to grow. Unlike other claims databases, APCD is unique in that it encompasses all payers of MA regardless of the insurance status. Therefore, it allows us to accurately detect both the cases and person-time at risk, which are critical for establishing the incidence and prevalence rates. Therefore, this unprecedented, populational claims database allows for the first time, a unique opportunity to measure the burden of ocular diseases in the US without relying on traditional epidemiological approaches such as surveys or populational sampling.

Our group in the University of Washington have <u>extensive experience and expertise in analyzing the electronic</u> medical record and claims data in combination with other large datasets (i.e. maps, census, meteorological

<u>data</u>) for ophthalmic research. We have published over 20 articles using EMR or claims databases in major peer-reviewed ophthalmology journals in last four years.[3–23] The methodologies that have been used in these previous studies will be critical in accomplishing the proposed work. We are familiar with the latest statistical methods including mixed linear modeling, Monte Carlo Markov Chain modeling for time-series data, deep learning, extreme gradient boosting, and Bayesian statistical methods. In addition, we have extensive experience translating the latest computer science concepts into ophthalmology such as deep learning applications.[21,22,24–26]

Our central hypothesis is that patient care-related medical informatics can be transformed into hypothesisgenerating databases for clinical research. By using the APCD data, we propose to use a purely data-driven approach to understand the epidemiology and risk factors of sight-threatening ophthalmic conditions (Aim 1) and to determine the factors related to the access, outcome and delivery of ophthalmic care in the state of MA (Aim 2).

Specific Aim 1. Determine the epidemiology of major sight-threatening conditions and their risk factors.

Aim 1A) Determine the incidence and prevalence of major sight-threatening conditions. Sight-threatening conditions in our proposal include diabetic retinopathy, age-related macular degeneration, glaucoma, cataract, corneal ulcer, uveitis, ocular trauma, and ocular melanoma. Aim 1B) Determine the socioeconomic, geospatial, and temporal risk factors associated with major sight-threatening conditions.

We will perform descriptive analyses and develop multivariate regression models to determine significant demographic, socioeconomic, and clinical risk factors. For additional environmental risk factors that are not contained within CHIA data, we will combine the dataset with available open-sourced meteorological and satellite data. We will determine whether geospatial and temporal/seasonal risks exist for the sight-threatening conditions using Hidden Markov Modeling and machine learning approaches. We hypothesize that the prevalence of ophthalmic conditions will differ between populations of varying geographic locations and insurance status, and certain conditions such as uveitis or ocular melanomas will be associated with geographic and seasonal risk factors.

Specific Aim 2. Determine the access, outcome, and delivery of care for major sight-threatening conditions.

Aim 2A) Determine the difference that exists in the access of care for the major sight-threatening conditions and their treatments. We will assess how much patients have to travel for their eye care and determine whether distance is associated with higher severity of sight-threatening conditions, systemic morbidities and mortality in a health care setting. Using Geographic Information Systems, we will map the zip codes to a GPS coordinate and use Open Street Map data to assess driving distance to the eye care provider. We hypothesize that limited access of care will be associated with increased severity of sight-threatening conditions specifically diabetic retinopathy, glaucoma, and age-related macular degeneration requiring more surgeries and higher overall mortality.

Aim 2B) Determine the difference that exists in the delivery of care and outcome for the major sight-threatening conditions and their treatments. We will compare the patterns of patient visit, referral patterns, treatment types and frequencies that may vary between providers, insurance status, and geographic locations. In order to understand the impact of these ophthalmic conditions, we will perform health economic analyses to establish the burden of treatment in the overall healthcare systems. We will perform descriptive analyses then build multivariate regression models to determine significant factors that contribute to delivery of care. In addition, we will apply machine learning approaches to identify potential risk factors associated with higher severities of major sight-threatening conditions. We hypothesize that the difference in types of providers and insurance status will be major determinants of the diagnoses of major sight-threatening conditions and associated treatments.

At the completion of the proposed studies, we will have a better understanding of current epidemiology and risk factors of ophthalmic diseases, real-world delivery of ophthalmic care, and factors related to the access of

ophthalmic care. These results may have important public health impact and implications in current ophthalmic care.

References

- 1. <u>Vision impairment and blindness [Internet]. [cited 2019 Jul 9]. Available from: https://www.who.int/news-room/fact-sheets/detail/blindness-and-visual-impairment</u>
- 2. <u>Thorne JE, Suhler E, Skup M, Tari S, Macaulay D, Chao J, Ganguli A. Prevalence of Noninfectious Uveitis in the United States: A Claims-Based Analysis. JAMA Ophthalmol. 2016 Nov 1;134(11):1237–45.</u>
- 3. <u>Lee CS, Kim AJ, Baughman D, Egan C, Bailey C, Johnston RL, Natha S, Khan R, Brand C, Akerele T, McKibbin M, Downey L, Al-Husainy S, Lee AY, Tufail A. VISUAL ACUITY IMPROVEMENT WHEN SWITCHING FROM RANIBIZUMAB TO AFLIBERCEPT IS NOT SUSTAINED. Retina.</u> 2018;38(5):951–6.
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- 5. <u>Lee AY, Lee CS, Egan CA, Bailey C, Johnston RL, Natha S, Hamilton R, Khan R, Al-Husainy S, Brand C, Akerele T, Mckibbin M, Downey L, Tufail A. UK AMD/DR EMR REPORT IX: comparative effectiveness of predominantly as needed (PRN) ranibizumab versus continuous aflibercept in UK clinical practice. Br J Ophthalmol. 2017;101(12):1683–8.</u>
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- 10. <u>Lee AY, Lee CS, Pieters M, Maa AY, Cockerham G, Lynch MG. Differences in Tertiary Glaucoma Care in the Veterans Affairs Health Care System. JAMA Ophthalmol. 2018;136(11):1227.</u>
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- 19. <u>Baughman DM, Su GL, Tsui I, Lee CS, Lee AY. Validation of the Total Visual Acuity Extraction Algorithm (TOVA) for Automated Extraction of Visual Acuity Data From Free Text, Unstructured Clinical Records. Transl Vis Sci Technol. 2017 Mar;6(2):2.</u>
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 <u>Associations between recent and established ophthalmic conditions and risk of Alzheimer's disease.</u>
 Alzheimers Dement. 2019 Jan;15(1):34–41.
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- 23. <u>Lin AD, Lee AY, Zhang Q, Rezaei KA, Kinyoun J, Wang RK, Lee CS. Association between OCT-based microangiography perfusion indices and diabetic retinopathy severity. Br J Ophthalmol. 2017</u>
 Jul;101(7):960–4.
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- 26. <u>Lee CS, Baughman DM, Lee AY. Deep Learning Is Effective for Classifying Normal versus Age-Related Macular Degeneration OCT Images. Ophthalmology Retina. 2017;1(4):322–7.</u>

CURRICULUM VITAE

Cecilia Lee, MD MS

July 10, 2019

PERSONAL DATA

Home Address: 9306 SE 72nd st

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Seattle WA 98104

Work Phone: 206-543-7250 Work email: leecs2@uw.edu

Place of birth: Seoul, South Korea

Citizenship: USA

Date of birth: 01/09/1981

EDUCATION

2014-2016 Masters of Science

Epidemiology, Clinical Research Track

University of Washington Seattle, WA

School of Public Health

2004-2008 Doctor of Medicine

Emory University School of Medicine Atlanta, GA

Mary W. Rautenbusch Scholar

2000-2004 Bachelors of Science, Biology

Emory University Atlanta, GA

Phi Beta Kappa
Summa Cum Laude

POST-GRADUATE TRAINING

2013-2014	Fellowship: Moorfields Eye Hospital Medical Retina	London, UK		
2012-2013	Fellowship: Washington University Uveitis	St. Louis, MO		
2009-2012	Residency: Emory University Ophthalmology	Atlanta, GA		
2008-2009	Internship: Emory University Transitional Year	Atlanta, GA		
FACULTY POSITION	ONS HELD			
2016- Present	University of Washington Assistant Professor, Medical Retina and Uveitis	Seattle, WA		
2015-2016	University of Washington Acting Assistant Professor, Medical Retina and Uveitis	Seattle, WA		
2014-2015	University of Washington Acting Instructor, Medical Retina and Uveitis	Seattle, WA		
2012-2013	Washington University Instructor, Comprehensive Ophthalmology	St. Louis, MO		
HOSPITAL STAFF	HOSPITAL STAFF APOINTMENTS			
2014 – present	Harborview Medical Center Active Medical Staff	Seattle WA		
2014 – present	UW Medical Center Active Medical Staff	Seattle WA		
2014 – present	Veteran's Administration PSHCS Associate Medical Staff	Seattle WA		
2014 – 2017	Seattle Children's Hospital Associate Medical Staff	Seattle WA		

HONORS & AWARDS

2019	ARVO/Alcon Early Career Clinician-Scientist Research Award
2018	AAO Leadership Development Program
2018	Latham Vision Research Innovation Award
2018	National Health Institute Loan Repayment Program Renewal Award
2017	Latham Vision Research Innovation Award
2017	National Health Institute Loan Repayment Program Renewal Award
2017	Teacher of the Year Award
2017	Seattle Federal Executive Boards' Public Service Honoree
2015	Latham Vision Research Innovation Award
2015	National Health Institute Loan Repayment Program Award
2014	European Society of Ophthalmology (SOE) Prize
2014	K23 Clinical Research Career Developmental Award
2013	Golden Apple Award "Best Fellow Teacher Award" Washington
2012	National Eye Institute Travel Grant
2011	AUPO Resident Research Course Travel Grant
2006	Best Research Presentation, Emory University School of Medicine
2004-2008	Mary W. Rautenbusch Scholar
2004	Summa Cum Laude
2003-2004	Phi Beta Kappa
2001	National Science Foundation Grant
2000-2004	Callaway Scholar
2000	Magma Cum Laude
	-

BOARD CERTIFICATION

2015-pres. American Board of Ophthalmology

CURRENT LICENSURE

2014-pres. Washington State Medical License

PROFESSIONAL ORGANIZATIONS

2014-pres.	American Academy of Ophthalmology (AAO)
2014-pres.	Association for Research in Vision and Ophthalmology (ARVO)
2014-pres.	Washington Academy of Eye Physicians and Surgeons (WAEPS)
2015-pres.	American Uveitis Society (AUS)
2016-pres.	American Society of Retina Specialists (ASRS)
2016-pres.	Ocular Microbiology and Immunology Group (OMIG)
2018-pres.	Women in Ophthalmology

EDITORIAL RESPONSIBILITIES

2016 – present	Ad-hoc reviewer Ophthalmology
2016 – present	Ad-hoc reviewer Ophthalmology Retina
2016 – present 03/01/2017 10/17/2017	Ad-hoc reviewer IOVS "Exceptionally Good Review" "Exceptionally Good Review"
2016 – present	Ad-hoc reviewer Ophthalmic Immunology and Inflammation
2016 – present	Ad-hoc reviewer Retina Cases and Brief Reports
2017 – present	Ad-hoc reviewer Computer Methods and Programs in Biomedicine
2017 – present	Ad-hoc reviewer Plos One
2017 – present	Ad-hoc reviewer Biomedical Optics Express
2017 – present	Ad-hoc reviewer Pathobiology of Aging and Age-related Diseases
2018 – present	Ad-hoc reviewer Ophthalmic Epidemiology
2018- present	Ad-hoc reviewer for Medical Science Monitor
2018- present	Ad-hoc reviewer American Journal of Ophthalmology
2019- present	Ad-hoc reviewer Computer Methods and Programs in Biomedicine
2020	Associate Editor, Journal of Alzheimer's Disease

INTERNATIONAL RESPONSIBILITIES

2016- present Advisory Honorary Board Member, Viraj Healthcare Foundation

NATIONAL RESPONSIBILITIES

10/2019	Organizer and moderator of OMIG symposium: "Recent Advances in Diagnosis and Treatment of Endophthalmitis." American Academy of Ophthalmology (AAO), San Francisco, CA
05/2019	Moderator of a paper session: "The gut-eye axis: emerging roles of the microbiome in ocular immunity and diseases." Association for Research in Vision and Ophthalmology (ARVO), Vancouver, Canada
04/2019	Organizer and moderator of ARVO/OMIG SIG: "Next generation sequencing for

Ophthalmology (ARVO), Vancouver, Canada

04/2019 NIH reviewer

2019/10 ZEY1 VSN (08)

Special Emphasis Panel/Scientific Review Group

2018- Present President, Ocular Microbiology and Immunology Group

10/2018 Moderator of OMIG symposium: "Non-bacterial keratitis."

American Academy of Ophthalmology (AAO), Chicago, IL.

10/2018 Moderator of OMIG research presentations

OMIG annual meeting, American Academy of Ophthalmology (AAO), Chicago, IL.

2017 - 2018 President-Elect, Ocular Microbiology and Immunology Group

2016 - 2017 Secretary, Ocular Microbiology and Immunology Group

05/2017 Moderator of a paper session: "Improving the care of diabetic retinopathy." Association

for Research in Vision and Ophthalmology (ARVO), Baltimore, MD.

06/2017 Early Investigator NIH reviewer

2017/10 ZRG1 BDCN-J (81)

Center for Scientific Review Special Emphasis Panel

LOCAL RESPONSIBILITIES

2016 – present Director of Clinical Trials, Department of Ophthalmology, UW

2016 – present Co-director of Resident Research, Department of Ophthalmology, UW

RESEARCH FUNDING

Dates of Award 12/2014-11/2019
Grant No. 1K23EY024921-01
Agency: National Eye Institute

Title: Ocular Surface Microbiome in Potentially Infectious

Ophthalmic Disease

Role: PI

Total Direct Costs: \$990,920

Cecilia S. Lee, MD, MS

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Dates of Award 08/2015-07/2016

Grant No. Latham Vision Research Innovation Award

Agency: University of Washington

Title: Ocular Surface Microbiome in Adenoviral Keratoconjunctivitis

Role: PI
Total Direct Costs: \$21,000

Dates of Award 07/2015-06/2017

Grant No. National Health Institute Loan Repayment Program

Agency: National Institute of Health

Title: Ocular Surface Microbiome in Adenoviral Keratoconjunctivitis

Role: PI
Total Direct Costs: \$75,000

Dates of Award 08/2017-07/2018

Grant No. Latham Vision Research Innovation Award

Agency: University of Washington

Title: Evaluation of vascular risk factors of Alzheimer's disease using OCTA

Role: Co-investigator (PI: Courtney Francis)

Total Direct Costs: \$10,000

Dates of Award 07/2017-06/2018

Grant No. National Health Institute Loan Repayment Program Renewal Award

Agency: National Institute of Health

Title: Ocular Surface Microbiome in Adenoviral Keratoconjunctivitis &

Endophthalmitis

Role: PI
Total Direct Costs: \$35,000

Dates of Award 08/2018-07/2019

Grant No. Latham Vision Research Innovation Award

Agency: University of Washington

Title: Evaluation of molecular risk factors of endophthalmitis

Role: PI Total Direct Costs: \$21,000

Dates of Award 07/2018-06/2020

Grant No. National Health Institute Loan Repayment Program Renewal Award

Agency: National Institute of Health

Title: Determination of molecular risk factors in endophthalmitis

Role: PI

Total Direct Costs: \$58,504.81

BIBLIOGRAPHY

Articles in Peer Reviewed Journals:

- 1. Bojikian K, Lee CS, Lee AY. Finding glaucoma in color fundus photographs using deep learning. JAMA ophthalmology. Accepted
- 2. Lee CS, Tyring AJ, Wu Y et al. Generating retinal flow maps from structural optical coherence tomography with artificial intelligence. Sci Reports. 2019. Accepted
- 3. Wen JC,* Lee CS,* Keane P, Xiao S, Rokem A, Chen P, Wu Y, Lee AY. Forecasting future Humphrey visual fields using deep learning. <u>Plos one.</u> Accepted. *co-first author.
- 4. **Lee CS**, Larson EB, Gibbons LE et al. Ophthalmology-based neuropathology risk factors: diabetic retinopathy is associated with deep microinfarcts in a community-based autopsy study. <u>Journal of Alzheimer's Disease</u>. 2019. In press. *corresponding author.
- 5. Kihara Y, Heeren TF, **Lee CS**, Wu Y, et al. Predicting retinal sensitivity from optical coherence tomography with deep learning in macular telangiectasia type 2. Jama Network open. 2019. In press.
- 6. Denniston A, Lee AY, Lee CS, Crabb D et al. The United Kingdom Diabetic Retinopathy Electronic Medical Record (UK DR EMR) Users Group: Report 4 Real world data for the impact of deprivation on the presentation of diabetic eye disease at hospital services. <u>British J Ophthalmol</u>. 2018. In press.
- 7. **Lee CS**,* Larson EB, Gibbons LE et al. Associations between Recent and Established Ophthalmic Conditions and Risk of Alzheimer's Disease. <u>Alzheimer's & Dementia</u>. 2018. In press. *corresponding author.
- 8. Lee AY, Lee CS,* Pieters MN, Cockerham G, Lynch M. Glaucoma Surgery in the Veterans Healthcare System. JAMA Ophthalmol. 2018. In press. *co-first author
- 9. **Lee CS,*** Lee AY, Akileswaran L et al. Determinants of Clinical Outcomes in Adenoviral Keratoconjunctivitis. <u>Ophthalmology.</u> 2018. 125(9):1344-1353. *corresponding author.
- 10. Balaratnasingam C, An D, Sakurada Y, **Lee CS** et al. Comparisons Between Histology and Optical Coherence Tomography Angiography of the Periarterial Capillary-Free Zone. <u>Am J Ophthalmol.</u> 2018;189:55-64.
- 11. Pepple KL, Nguyen MH, Pakzad-Vaezi K, Williamson K, Odell N, **Lee CS**, Leveque T, Van Gelder RN. Response of Inflammatory Cystoid Macular Edema to Treatment with Oral Acetazolamide. <u>Retina.</u> 2019. In press.
- 12. Lee CS, Rokem A, Lee AY. Letter to editor. Ophthalmol Retina. 2018. Accepted for publication.
- 13. Lee AY, Butt T, Chew E, Agron E, Clemons T, Egan C, **Lee CS**, Tufail A. Cost-effectiveness of age-related macular degeneration study supplements in the UK: combined trial and real-world outcomes data. <u>Br J Ophthalmol</u>. 2018.102(4):465-472.
- 14. Lee CS, Kim JA, Baughman D et al. Visual acuity improvement when switching from ranibizumab to aflibercept is not sustained. Retina. 2018;38:951-956.
- 15. Xiao S, Bucher F, Wu Y, Rokem A, Lee CS et al. Fully automated segmentation of mice oxygen induced retinopathy retinal images using deep convolutional neural networks. JCI Insight. 2017;21:2(24).
- 16. **Lee CS**, Tyring AJ, Deruyter NP, et al. Deep-learning based, automated segmentation of macular edema in optical coherence tomography. <u>BiomedOpt Express</u>. 2017;8(7).
- 17. **Lee CS**, Su GL, Baughman DM, Wu U, Lee AY. Disparities in delivery of ophthalmic care: An exploration of public Medicare data. <u>PLoS One.</u> 2017;12:e0182598.
- Lee CS, Lee AY, Baughman DM et al. The United Kingdom Diabetic Retinopathy Electronic Medical Record Users Group: Report 3: Clinical Features Predict Progression of Diabetic Retinopathy. <u>Am J Ophthalmol</u>. 2017;180:64-71.
- Su G, Baughman DM, Lee AY, Lee CS. Comparison of retina specialist preferences regarding Spectral Domain and Swept-Source Optical Coherence Tomography Angiography. <u>Clin Ophthalmol</u>. 2017; 11:889-895
- 20. Lee AY, Lee CS,* Egan C, et al. UK AMD/DR EMR Report IX: Comparative effectiveness of predominantly PRN ranibizumab versus continuous aflibercept in UK clinical practice. <u>Br J Ophthalmol</u>. 2017;101:1683-1688. *co-first author and the corresponding author
- 21. Lee CS, RN Van Gelder, Lee AY. Letter to editor. Ophthalmology. 2017. 124(7):e65-e66.

- 22. Baughman DM, Snydsman B. Lee CS. Jung HC. Bilateral uveitis and keratitis following nivolumab treatment for metastatic melanoma. <u>Medical Case Reports</u>. 2017.3(2).
- 23. Baughman D, Su G, Tsui I, **Lee CS**,* Lee AY.* Validation of the TOtal Visual acuity extraction Algorithm (TOVA) for automated extraction of visual acuity data from free text, unstructured clinical records. <u>Transl Vis Sci Technol</u>. 2017;6(2):2. *co-senior author.
- 24. **Lee CS**, Baughman D, Lee AY. Deep learning is effective for the classification of OCT images of normal versus Age-related Macular Degeneration. <u>Ophthalmol Retina</u>. 2017;1:322-327.
- 25. Lee J, Agarwal A, Mahendradas P, **Lee C**, Gupta V, Pavesio C, Agrawal R. Viral Posterior Uveitis. <u>Surv</u> Ophthalmol. 2017;62:404-445.
- 26. Lin A, Lee AY, Zhang Q, Rezaei K, Wang RK, Lee CS. Association between OCT-based microangiography perfusion indices and diabetic retinopathy severity. Br J Ophthalmol. 2017;101:960-964.
- 27. Zhang Q, Zhang A, Lee CS, et al. Projection artifact removal improves visualization and quantitation of macular neovascularization imaged by optical coherence tomography angiography. Ophthalmol Retina. 2017:1:124-136.
- 28. Ho CW, Agrawal R, Agarwal A, Gupta V, Lee C, et al. A review of the role of intravitreal corticosteroids as an adjuvant to antibiotics in infectious endophthalmitis. Ocul Immunol Inflamm. 2016.16;1-8.
- 29. Lee AY, Zhang Q, Mudumbai R, Wang RK, **Lee CS**. Evaluation of bilateral central retinal artery occlusions with ocular coherence tomography based microangiography (OMAG): a case report. <u>J Med Case Rep.</u> 2016;10:307.
- 30. Lee CS, Lee AY, Holland GN, Van Gelder RN, Tufail A. Big data and uveitis. Ophthalmology. 2016:123:2273-2275.
- 31. Lee CS, Morris A, Van Gelder RN, Lee AY. Evaluating access to eye care in the contiguous United States by calculated driving time in the US medicare population. Ophthalmology. 2016;123:2456-2461.
- 32. Lee CS, Randhawa S, Lee AY, Lam DL, Van Gelder RN. Patterns of laboratory testing utilization among uveitis specialists. Am J Ophthalmol. 2016;170:161-167.
- 33. Doan T, Akileswaran L, Anderson D, Johnson B, Ko N, Shrestha A, Shestopalov VI, **Lee CS**, Lee AY, Van Gelder RN. Paucibacterial microbiome and resident DNA virome of the healthy conjunctiva. <u>Invest Ophthalmol Vis Sci.</u> 2016;57:5116-5126.
- 34. Lee AY, Lee CS, Van Gelder RN. Scalable metagenomics alignment research tool (SMART): a scalable, rapid, and complete search heuristic for the classification of metagenomic sequences from complex sequence populations. BMC Bioinformatics. 2016;17:292. PMC 4963998
- 35. Tan HY, Agarwal A, **Lee CS** et al. Management of noninfectious posterior uveitis with intravitreal drug therapy. Clinical Ophthalmol. 2016;10:1983-2020.
- 36. Liew G, Lee AY, Zarranz-Ventura J, Stratton I, Bunce C, Chakravarthy U, Lee CS, Keane PA et al. The UK neovascular AMD database report 3: inter-centre variation in visual acuity outcomes and establishing real-world measures of care. Eye. 2016;30:1462-1468.
- 37. Lee AY, Lee CS, Keane PA, Tufail A. Use of mechanical turk as a mapreduce framework for macular OCT segmentation. <u>J Ophthalmol.</u> 2016;2016:6571547.
- 38. Zhang q,* Lee CS,* Chao J, et al. Wide-field optical coherence tomography based microangiography for retinal imaging. Sci Rep. 2016;6:22017. *First co-authors.
- 39. Kee AR, Gonzalez-Lopez JJ, Al-Hity A, Gupta B, Lee CS et al. Anti-tubercular therapy for intraocular tuberculosis: A systematic review and meta-analysis. <u>Surv Ophthalmol.</u> 2016; 5: 628-53.
- 40. Agrawal R, **Lee CS**, Gonzalez-Lopez JJ et al. Flubiprofen: a nonselective cyclooxygenase inhibitor for treatment of noninfectious, non-necrotizing anterior scleritis. Ocular Infection and Immunology. 2015;26:1-8.
- 41. Lee CS, Harocopos G Kraus CL, Lee AY, Couch S, Rao PK. IgG4- associated Orbital and Ocular inflammation. J Ophthalmic Inflamm Infect. 2015;5:15. doi: 10.1186/s12348-015-0047-y
- 42. Lee AY,* Lee CS,* Butt T, Xing W, Johnston RL, Chakravarthy U, Egan C, Akerele T, McKibbin M, Downey L, Natha S, Bailey C, Khan R, Antcliff R, Varma A, Kumar V, Tsaloumas M, Mandal K, Liew G, Keane PA, Sim D, Bunce C, Tufail A; UK AMD EMR Users Group. UK AMD EMR USERS GROUP

- REPORT V: benefits of initiating ranibizumab therapy for neovascular AMD in eyes with vision better than 6/12. <u>Br J Ophthalmol.</u> 2015; 99(8):1045-50. *Co-first authors
- 43. Butt T, Lee AY, Lee CS, Tufail A. Is initiating ranibizumab therapy for neovascular AMD in eyes with vision better than 6/12 cost-effective? An economic model using real world outcomes from the UK AMD EMR USERS GROUP." <u>BMJ Open.</u> 2015; 5(5) doi: 10.1136/bmjopen-2014-006535.
- 44. Hong B, Lee CS, Van Gelder RN, Garg S. Emerging techniques for pathogen discovery in endophthalmitis. Curr Opin Ophthalmol. 2015; 26:221-5.
- 45. Lee CS, Agrawal R, Pavesio C. Ocular Tuberculosis, a clinical conundrum. <u>Ocul Immunol Inflamm.</u> 2015: 19:1-6.
- 46. **Lee CS,** Lee AY, Sim DA, Keane PA, Mehta H, Zarranz-Ventura J, Fruttiger M, Egan CA, Tufail A. Reevaluating the Definition of Intraretinal Microvascular Abnormalities and Neovascular Complexes in Diabetic Retinopathy using Optical Coherence Tomography and Fluorescein Angiography. <u>Am J Ophthalmol.</u> 2015:159(1):101-10.
- 47. Agrawal R, **Lee CS**, Phatak S, Pavesio C. Immunopharmacotherpay of non-infectious uveitis: where do we stand? Expert Opin Biol Ther. 2014;14(12):1719-22.
- 48. Earl J,* Lee CS,* Yom V, Van Stavern GP, Abuattieh M, Chin-Yee D, Rao PK, Apte RS. Visual Cycle Suppression via Patching in Central Serous Chorioretinopathy. Ophthalmology. 2014:121(12);2502-2504. *Co-first author
- 49. Lee CS, Lee AY, Forooghian F, Bergstrom CS, Yan J, Yeh S. Fundus autofluorescence features in the inflammatory maculopathies. Clinical Ophthalmol. 2014:8;2001-2012.
- 50. **Jung CS**, Walrath JD, Hudgins PA, Wojno T. Diffuse Symmetric Meningioma en Plaque Mimicking Metabolic Disease. Orbit. 2012;31:341-3.
- 51. **Jung CS**, Payne JF, Bergstrom C, Crbbs B, Yan J, Hubbard GB, Olsen TW, Yeh S. Multimodality Diagnostic Imaging in Unilateral Acute Idiopathic maculopathy <u>Arch Ophthalmol</u>. 2012;130(1):50-6.
- 52. **Jung CS**, Hubbard GB 3rd, Grossniklaus HE. Giant Cell Astrocytoma of the Retina in a 1-month-old infant. J Pediatr Ophthalmol Strabismus. 2009;2:1-4.
- 53. **Jung CS**, Bruce B, Newman NJ, Biousse V. Visual field defects in non-arteritic anterior ischemic optic neuropathy: effect of Vision Restoration Therapy (VRT)- a pilot study. <u>J Neurol Sci.</u> 2008;268:145-9.
- 54. **Jung CS**, Zhou Z, Khuri FR, Sun S. Assessment of apoptosis-inducing effects of docetaxel combined with the proteasome inhibitor PS-341 in human lung cancer cells. <u>Cancer Biology & Therapy</u>. 2007;6(5).

Book Chapter:

Jung CS, Grossniklaus HE, Hutchinson, A. Lead editor of Chapter # 11, Iris, the Anatomy Section of Volume 1 of *Duane's Foundations of Clinical Ophthalmology* 2012.

Other Publications:

Biousse V, Newman NJ. *Neuro-Ophthalmology Illustrated*. New York: Thieme. 2009. (One of three proofreaders of the book).

Lee CS, Lee AY, Rao PK. A Worldwide Survey of Uveitis. Retina Times. 2013;31(3) 32-35.

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Abstracts:

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- 2. Kihara Y, Heeren T, Wu Y, Spaide T, Egan C, Lee CS, Lee AY. Automated machine learning pipeline for predicting retinal sensitivity from optical coherence tomography in macular telangiectasia type 2. Association for Research in Vision and Ophthalmology (ARVO), April 2019.
- 3. Gencarella M, Jung H, Lee CS, Lee AY. Predictors of baseline diabetic retinopathy severity at Veterans Affairs teleretinal screening program over a 10-year period. Association for Research in Vision and Ophthalmology (ARVO), April 2019.
- 4. **Lee CS**, Larson EB, Gibbons LE, et al. Ophthalmology-based AD risk factors: diabetic retinopathy is associated with deep microinfarcts in a community-based autopsy study. The Alzheimer's Association International Conference (AAIC), Chicago, 2018.
- 5. Vangipuram G, Egan C, Lee AY, Lee CS. Capcha performance in active macular disease. Association for Research in Vision and Ophthalmology (ARVO), May 2018.
- 6. **Lee CS**, Gibbons LE, Lee AY, Bowen JD, McCormick W, McCurry SM, Larson EB, Crane PK. Ophthalmology-based AD risk factors: glaucoma, age-related macular degeneration, and diabetic retinopathy are each associated with AD risk in a community-based cohort study. The Alzheimer's Association International Conference (AAIC), London, UK, 2017.
- Baughman DM, Lee CS, Lee AY. Validation of the TOtal Visual acuity extraction Algorithm (TOVA)
 for automated extraction of visual acuity and intraocular
 pressure data from free text clinical records. Association for Research in Vision and Ophthalmology
 (ARVO), May 2017.
- 8. Su GL, Baughman DM, Zhang Q, Rezaei K, Lee AY, Lee CS. Comparison of Retina Specialist Preferences Regarding Spectral Domain and Swept-Source Optical Coherence Tomography Angiography. Imaging Conference. Association for Research in Vision and Ophthalmology (ARVO), May 2017.
- 9. Pakzad-Vaezi K, Nguyen M, Lee C, Pepple KL, Bryan A. Laboratory analysis and predictive characteristics of infectious panuveitis sampling in the Pacific Northwest. Association for Research in Vision and Ophthalmology (ARVO), May 2017.
- 10. Lee CS, Lee AY, Baughman D, Tufail A, Egan C. Baseline severity and clinical features predict progression to PDR and VH. Controversies in Ophthalmology, February 2017. Seoul, Korea
- 11. Ko N, Lee AY, Zhang Q, Rezaei K, Mudumbai R, Wang RK, Lee CS. Evaluation of retinal artery occlusions with ocular coherence tomography based microangiography. Association for Research in Vision and Ophthalmology (ARVO), May 2016.
- 12. Lin A, Zhang Q, Lee AY, Rezaei K, Kinyoun J, **Lee CS**, Wang RK. Correlation between OCT-based microangiography flow indices and diabetic retinopathy. Association for Research in Vision and Ophthalmology (ARVO), May 2016.
- 13. Wang R, Zhang Q, Lee CS, Attaran-Rezaei K, Rosenfeld P. The features of age-related macular degeneration imaged by optical coherence tomography based angiography. Association for Research in Vision and Ophthalmology (ARVO), May 2016.
- 14. Lee AY, Lee CS, Weigngeist AP, Van Gelder RN. Evaluation of access to eye care by driving time in the state of Washington. Association for Research in Vision and Ophthalmology (ARVO), May 2016.
- 15. **Lee CS**, Lee AY, Akileswaran L, Stroman D, Najfi-Tagol K, Kleiboeker S, Wald A, Van Gelder RN. The evaluation of worldwide distribution of adenoviral genotypes in acute/epidemitc keratoconjunctivitis and adenvoiral-negative keratoconjunctivitis with next generation sequencing. Association for Research in Vision and Ophthalmology (ARVO), May 2016.

- 16. **Lee CS**, Galor A, Tuzhikov A, Shestopalov V, Van Gelder RN. Quantification of 16S Bacteria and Torque Teno Virus in Dry Eye Syndrome and Clinical Correlations, Association for Research in Vision and Ophthalmology (ARVO), May 2015.
- 17. **Lee CS,** Lee AY, Tufail A. UK AMD EMR USERS GROUP REPORT V: Benefits of initiating Ranibizumab Therapy for Neovascular AMD in Eyes with Vision Better than 6/12. Annual Meeting Royal college of ophthalmology. Liverpool, UK 2015.
- 18. Zhang Q, Lee CS, Huang Y, Razaei K, Chao J, Munsen R, Kinyoun J, Wang RK. OCT-based microangiography of diabetic retinopathy. Association for Research in Vision and Ophthalmology (ARVO), May 2015.
- 19. Tufail A, Lee CS, Lee AY. UK AMD EMR USERS GROUP REPORT V: Benefits of initiating Ranibizumab Therapy for Neovascular AMD in Eyes with Vision Better than 6/12. Association for Research in Vision and Ophthalmology (ARVO), May 2015.
- 20. Lee AY, Lee CS. Big data visualization in cataract disparity. Association for Research in Vision and Ophthalmology (ARVO), May 2015.
- 21. Chu Z, Zhang Q, Chen C, Luo A, **Lee CS**, Kinyoun J, Wang RK. Repeatability and reproducibility of quanitifying parafoveal vessel density in normal subjects with OCT_based microangiography. Association for Research in Vision and Ophthalmology (ARVO), May 2015.
- 22. Durbin MK, Lee S, Lee CS, Zhang Q, Chung P, Rezaei K, Laron M, An L, Wang RK. Evaluation of neovascularization elsewhere using optical coherence tomography based microangiography. Association for Research in Vision and Ophthalmology (ARVO), May 2015.
- 23. Wang RK, Zhang Q, **Lee CS**, Huang Y, Razaei K, Munsen R, Chao J, Kinyoun J. Evaluation of agerelated macular degeneration and polypoidal choroidal vasculopathy using OCT-bsed microangiography. Association for Research in Vision and Ophthalmology (ARVO), May 2015.
- 24. **Lee CS**, Carreno E, Fernandez-Sanz G, Lee AY, Cook C, Nemeth T, Dattani R, Lee RWJ, Pavesio C. Increased Risk of Post-Cataract Endophthalmitis in Uveitis Patients A Retrospective 10 Year Study; Are They More Susceptible for Misdiagnosis & Overtreatment? Association for Research in Vision and Ophthalmology (ARVO), May 2014.
- 25. Lee AY, Lee CS, Keane PA, Tufail A. Association for Research in Vision and Ophthalmology (ARVO), May 2014.
- 26. Kumar G, Lee AY, Lee CS. Refractive Surgical Outcomes of Cataract Surgeons in Training. Association for Research in Vision and Ophthalmology (ARVO), May 2013.
- 27. **Lee CS**, Lee AY, Bhorade A, Karacal H. Tube Shunt versus Trabeculectomy Surgery in Patients with Glaucoma Associated with Ocular Inflammation. Association for Research in Vision and Ophthalmology (ARVO), May 2013.
- 28. Sawhney GK, **Jung CS**, Scott MN, Yeh S. Diagnostic Yield of Serologic and Radiologic Tests in the Evaluation of Patients with White Dot Syndromes. Association for Research in Vision and Ophthalmology (ARVO), May 2012.
- 29. **Jung CS**, Payne JF, Bergstrom C, Cribbs B, Yan J, Hubbard GB, Olsen TW, Yeh S. Multimodality Diagnostic Imaging in Unilateral Acute Idiopathic Maculopathy., Association for Research in Vision and Ophthalmology (ARVO), May 2011.
- 30. **Jung CS**, Bruce B, Newman NJ, Biousse V. Visual field defects in non-arteritic anterior ischemic optic neuropathy: effect of Vision Restoration Therapy (VRT)- a pilot study. American Medical School Association (AMSA). Washington D.C., March 2007.

31. **Jung CS**, Bruce B, Newman NJ, Biousse V. Visual field defects in non-arteritic anterior ischemic optic neuropathy: effect of Vision Restoration Therapy (VRT)- a pilot study. North American Neuro-Ophthalmology Society (NANOS). Snowbird, UT. February 2007.

TEACHING RESPONSIBILITIES

2016 2017	IIW Madical Cabaal Commissions
2016 - 2017	UW Medical School Curriculum

Role: Created retina reading material for the curriculum, participated in the didactic

lecture and case study presentations each year

2016 – present Medical Student Case Presentation

Role: Review cases with medical students in ophthalmology rotation yearly

2016 – present **Ophthalmology Oral Boards Review**

Annual four-week course including lectures and mock exams for preparation of Oral

Boards

Role: Co-creator and co-presenter of the lectures (50%)

2017 – present **Resident Research Curriculum**

Annual four-week course including lectures and mock exams for preparation of Oral

Boards

Role: Co-director of the clerkship (40%), 2 hour didactic presentation, participation in research meetings with resident in the research rotation with Drs. Pepple and Van Gelder,

participation in the quarterly resident research discussion sessions.

RECENT CME

2018	American Association of Ophthalmology annual meeting, Chicago IL
2018	American Society of Retina Specialists annual meeting, Vancouver BC
2017	American Association of Ophthalmology annual meeting, New Orleans, LA
2017	Association for Research in Vision and Ophthalmology annual meeting, Baltimore,
	MD

MENTORSHIP

2017 – present Gautam Vangipuram; Ophthalmology Resident

Project: Evaluation of CAPCHA in macular diseases

Outcome: Manuscript submitted to Journal of Ophthalmology

Role: Primary mentor

2016 – 2018 Ariel Tyring; Ophthalmology Resident

Project: Applications of deep learning in quantifying intraretinal fluid in OCT

Outcome: Manuscript published in Biomed. Optic Express

Role: Co-mentor with Dr. A. Lee

2015 – 2017 **Bryan Yue**; Undergraduate Student

Project: Ocular Virome in Endophthalmitis Outcome: Paper Presentation at ARVO 2017

Role: Primary mentor

2016 – 2017 Grace Su: Medical Student

Project: Evaluation of Swept-source vs. Spectral Domain OCT Angiography

Outcome: Manuscript Published in Clinical Ophthalmology

Poster presentation at ARVO 2017 Role: Co-mentor with Dr. A. Lee

2016 – 2017 **Douglas Baughman**; Medical Student

Project 1: Evaluation of Bilateral CRVO with OCT Angiography Outcome: Manuscript published in Journal of Medical Case Reports

Role: Primary mentor

Project 2: Use of automated visual acuity extraction

Outcome: Manuscript published in Translational Vision Science and Technology;

Recipient of ARVO Travel Grant Award

Role: Primary mentor

2016 Aneesha Morris; Undergraduate Student

Project: Evaluating Access to Eye Care in the Contiguous United States

by Calculated Driving Time in the US Medicare Population Outcome: Manuscript

Published in Ophthalmology Role: Primary mentor

2016 **Jion Kim**; Undergraduate Student

Project: Tachyphylaxis in chronic anti-VEGF treatment for Neovascular AMD

Outcome: Manuscript accepted in Retina

Role: Primary mentor

2016 Alexander Lin; Ophthalmology Resident

Project: Evaluation of Flow Indices in Diabetic Retinopathy using OCT Angiography

Outcome: Manuscript published in British Journal of Ophthalmology

Role: Primary mentor

INVITED LECTURES

International Lectures

02/2017 Severance Hospital, Yonsei University Seoul, South Korea

Clinical Applications of Big Data in Ophthalmology

12/2015 Third International Meeting on OCT

Rome, Italy

Angiography, advances in OCT, and En face OCT, Wide-field ocular coherence tomography (OCT)

angiography in diabetic retinopathy Lee CS, Zhang Q, Wang R

National Lectures

04/2019	Association for Research in Vision and Ophthalmology (ARVO)	Vancouver, Canada
	American Uveitis Society Annual meeting	
	Objective measurement of AC cell counting using deep learning	
	Legocki A, Wu Y, Carreno E, Perez-Merino P, Munoz N, Pepple KL,	
	Holand GN, Egan C, Lee AY, Lee CS	
04/2019	Association for Research in Vision and Ophthalmology (ARVO)	Vancouver, Canada
	Annual Meeting	
	Genomic and gene expression analyses of pathogens in post-surgical	
	endophthalmitis. Lee CS, Kasi S, Akileswaran et al.	
	Fully automated artificial intelligence (AI) pipeline for feature-based	
	segmentation and classification of diabetic retinopathy in fundus phot	ographs.
	Wu Y, Wang F, Xiao S, Kihara Y, Spaide T, Lee CS, Lee AY.	
03/2019	UCLA/AUS workshop on Objective Measures of Intraocular	
03/2017	Inflammation for Use in Clinical Trials	Los Angeles, CA
	Objective measurement of AC cell counting using deep learning	Los imgeres, err
	Wu Y, Carreno E, Perez-Merino P, Legocki A, Munoz N, Pepple KL,	
	Holand GN, Egan C, Lee AY, Lee CS	
05/2018	Association for Research in Vision and Ophthalmology (ARVO)	Honolulu, HI
	Annual Meeting	
	Web based, fully automated, deep learning segmentation of oxygen	
	induced retinopathy Xiao S, Bucher F, Wu Y, Rokem A, Lee C et al.	
	Fully automated quantification of retinal cones and anterior chamber	r
	cells using deep learning. Wu Y, Xiao S, Rokem A, Lee C et al.	
11/2017	American Academy of Ophthalmology (AAO)	New Orleans, LA
	Ocular Microbiology and Immunology Group (OMIG)	
	Annual Meeting	
	Associations between clinical outcomes and molecular diagnoses of	
	post-surgical endophthalmitis Lee CS, Kasi S, Hong B et al.	
08/2017	Adult Changes in Thought (ACT) symposium	Seattle, WA
	Associations between ophthalmological conditions and the risk of	
	Alzheimer's disease Lee CS, Gibbons L, Lee AY et al.	
05/2017	Association for Research in Vision and Ophthalmology (ARVO)	Baltimore, MD

Annual Meeting

Baseline severity and clinical features predict progression to PDR and VH Lee CS, Lee AY, Baughman D, Tufail A, Egan C

Molecular diagnostic evaluation of post-surgical endophthalmitis Yue B, Lee CS, Lee AY et al.

05/2017 **Association for Research in Vision and Ophthalmology** (ARVO)

Baltimore, MD

Women in Retina Meeting

Comparative effectiveness of predominantly PRN ranibizumab and continuous aflibercept Lee CS, Lee AY, Egan C, Tufail A

Ocular Microbiology and Immunology Group (OMIG)

11/2016 American Academy of Ophthalmology (AAO)

Chicago, IL

Annual Meeting

Association of clinical outcomes with molecular adenoviral species in acute keratoconjunctivitis Lee CS, Lee AY, Akileswaran L, Stroman D, Najfi-Tagol K, Kleiboeker S, Wald A, Van Gelder RN

06/2016 Federation of Clinical Immunology Societies (FOCIS)

Boston, MA

Local microbiome in dry eyes and conjunctivitis Lee CS, Lee AY, Wald A, Van Gelder RN

05/2016 Association for Research in Vision and Ophthalmology (ARVO)

Seattle, WA

Annual Meeting

OCT-based angiography of choroidal neovascularization by removing projection artifacts Zhang Q, Zhang Q, Lee CS, Lee AY, Roisman L, Gregroi G, Durbin MK, An L, Stetson PF, Rosenfeld PJ, Wang RK

The features of age-related macular degeneration imaged by optical coherence tomography based angiography Wang R, Zhang Q, Lee CS, Attaran-Rezaei K, Rosenfeld P

05/2015 Association for Research in Vision and Ophthalmology (ARVO)

Denver, CO

Annual Meeting

OCT-based microangiography of diabetic retinopathy

Zhang Q, Lee CS, Huang Y, Razaei K, Chao J, Munsen R, Kinyoun J, Wang RK

Quantification of 16S Bacteria and Torque Teno Virus in Dry Eye Syndrome and Clinical Correlations
Lee CS, Galor A, Tuzhikov A, Shestopalov V, Van Gelder RN

10/2013 American Academy of Ophthalmology (AAO) Chicago, IL

**American Uveitis Society Meeting*

Fundus Autofluorescence and Indocyanine Green Angiography

Characteristics in Acute Posterior Multifocal Placoid Pigment Epitheliopathy

Lee CS, Palejwala NV, Lee AY, Albini T, Yeh S

O5/2012 Association for Research in Vision and Ophthalmology (ARVO) Ft. Lauderdale, FL

Fundus Autofluorescence Features in the Inflammatory Maculopathies

Jung CS, Lee AY, Forooghian F, Bergstrom CS, Yan J, Yeh S

Regional Lectures

09/2015 Gained in Translation Portland, OR

Annual Meeting

Clinical application of next generation sequencing in

adenoviral keratoconjunctivitis

Lee CS, Lee AY, Wald A, Van Gelder RN

05/2013 Midwest Uveitis Society Meeting St. Louis, MO

Diagnostic and Management Challenges

Lee CS, Rao PK

Local Lectures

Northwest Retina Club Seattle, WA

Quarterly Meeting

03/2016 Ocular manifestations of Takayasu's syndrome 10/2016 Autosomal Recessive Bestrophinopathy

09/2015 Unusual Retinochorioiditis

Curriculum Vitae

Date: June 26, 2019

Personal Information:

Aaron Y. Lee 9603 SE 72nd St

Mercer Island WA 98040

<u>leeay@uw.edu</u> 206-214-7890 (c)

Place of birth: Fayetteville, AR

Citizenship: US

Education:

Sept. 2007-June 2009 Washington University School of Medicine, St. Louis MO

Masters of Science in Clinical Investigations Degree

Sept. 2004-June 2009 Washington University School of Medicine, St. Louis MO

Doctor of Medicine Degree

Sept. 2000-June 2004 Harvard University, Cambridge MA

B.A., Biochemistry

Postgraduate Training:

July 2014-June 2015 University of British Columbia, Vancouver CA

Surgical Retina Fellowship

July 2013-June 2014 Moorfields Eye Hospital, London UK

Medical Retina Fellowship

July 2010-June 2013 Washington University School of Medicine, St. Louis MO

Ophthalmology Residency

July 2009- June 2010 St. John's Mercy Medical Center, St. Louis MO

Transitional Year Internship

Faculty Positions Held

2015 – Present Assistant Professor of Ophthalmology

University of Washington, Seattle, WA

Hospital Positions Held:

2015- Present Active Medical Staff, Ophthalmology

VAPSHCS, Seattle, WA

Aaron Y Lee, MD MSCI April 1st 2019 Page 2

2015- Present Active Medical Staff, Ophthalmology

Harborview Medical Center, Seattle, WA

2015- Present Active Medical Staff, Ophthalmology

University of Washington Medical Center, Seattle, WA

Honors:

2000-2004 Harvard University, Cambridge MA

High Honors, magna cum laude

John Harvard Scholarship for Group I Excellence by Harvard College

Top 100 in a worldwide online programming competition by TopCoder.com

Medical School

The Doctor William Ellis Research Prize in Ophthalmology
 Doris P. and Harry I. Wexler Research Prize in Ophthalmology

2007 Korean American Medical Association Scholar

Residency

2013	Ron Burde "Good Egg" Award
2013	Rosenbaum Research Award
2013	AUPO Resident Research Award
2012	Heed Resident Research Award

The Pepose Young Investigator Research Award

2011 ARVO Travel Grant Recipient
2011 Jules Stein Travel Grant Recipient

2011 Travel Grant Recipient for Regional Table Rock Conference

Fellowship

2015 UBC - Best Fellow Teaching Award

Honorary Research Fellow - University College London, London UK

Honorary Research Fellow - City University, London UK

Honorary Research Fellow - Moorfields Eye Hospital, London UK

2017 ARVO Young Clinician Scientist Award

2018 AAO Achievement Award 2019 AAO Secretariat Award

Board Certification:

2014 American Board of Ophthalmology

Current License to Practice:

Washington State

Professional Organizations:

Aaron Y Lee, MD MSCI April 1st 2019 Page 3

American Academy of Ophthalmology American Society of Retina Specialists

Teaching Responsibilities:

UW Vitreoretinal Surgery Fellowship Trainees:

2015-2016: Trucian Ostheimer 2017-2019: Steven Saraf 2018-2020: Ariel Tyring

Editorial Responsibilities:

IEEE Big Data Computing Service and Applications – Program Committee Member 2015 – 2017 AJO Editorial Board Member 2019 – Current TVST Editorial Board Member 2019 – Current Nature Scientific Reports Editorial Board Member 2019 – Current

Special National Responsibilities:

American Academy of Ophthalmology – Medical Information Technology Committee American Academy of Ophthalmology – State Society Big Data Consultant 2016-2017 American Academy of Ophthalmology – IRIS Analytics Task Force 2015-2016 American Academy of Ophthalmology – Leadership Development Program 2019- Current American Academy of Ophthalmology – AI Taskforce

Special Local Responsibilities:

WAEPS – Guest Speaker series 2016-Current

Research Funding:

Novartis 2016-2019: Collaboration with Moorfields Eye Hospital, University College London.

NVIDIA 2016-2017: Hardware donation for clinical research

Microsoft 2016-2017: Cloud computing credit for clinical research

Lowry Medical Research Institute 2017-Current: Phenotyping UK Biobank for MacTel using AI.

NIH K23 2018-Current: Risk factors for Diabetic Macular Edema.

Carl Zeiss Meditech Inc 2018-Current: OCT enhancement using Machine Learning.

Research to Prevent Blindness Career Development Award 2018 - Current

Alcon Research Institute: Young Investigator Award 2019

Latham Vision Research Innovation Award 2019

Past funding:

2007-2009 NIH T32 / KL12 Predoctral Clinical Research Training Grant

Bibliography:

Peer Reviewed Publications:

Boland MV, Hwang TS, Lim MC, Peterson JL, Lum F, **Lee AY**. Medicare Incentive Payments to United States Ophthalmologists for Use of Electronic Health Records: 2011-2016. Ophthalmology. 2019 Jul;126(7):928-934. doi: 10.1016/j.ophtha.2019.01.030. Epub 2019 Feb 13. PubMed PMID: 30768941.

Fasler K, Moraes G, Wagner S, Kortuem KU, Chopra R, Faes L, Preston G, Pontikos N, Fu DJ, Patel P, Tufail A,

Lee AY, Balaskas K, Keane PA. One- and two-year visual outcomes from the Moorfields age-related macular degeneration database: a retrospective cohort study and an open science resource. BMJ Open. 2019 Jun 21;9(6):e027441. doi: 10.1136/bmjopen-2018-027441. PubMed PMID: 31230012.

Lee CS, Tyring AJ, Wu Y, Xiao S, Rokem AS, DeRuyter NP, Zhang Q, Tufail A, Wang RK, **Lee AY.** Generating retinal flow maps from structural optical coherence tomography with artificial intelligence. Sci Rep. 2019 Apr 5;9(1):5694. doi: 10.1038/s41598-019-42042-y. PubMed PMID: 30952891; PubMed Central PMCID: PMC6450899.

Wen JC, Lee CS, Keane PA, Xiao S, Rokem AS, Chen PP, Wu Y, Lee AY. Forecasting future Humphrey Visual Fields using deep learning. PLoS One. 2019;14(4):e0214875. doi: 10.1371/journal.pone.0214875. eCollection 2019. PubMed PMID: 30951547; PubMed Central PMCID: PMC6450620.

Balaratnasingam C, An D, Sakurada Y, Lee CS, **Lee AY,** McAllister IL, Freund KB, Sarunic M, Yu DY. Comparisons Between Histology and Optical Coherence Tomography Angiography of the Periarterial Capillary-Free Zone.

Kihara Y, Heeren TFC, Lee CS, Wu Y, Xiao S, Tzaridis S, Holz FG, Charbel Issa P, Egan CA, **Lee AY.** Estimating Retinal Sensitivity Using Optical Coherence Tomography With Deep-Learning Algorithms in Macular Telangiectasia Type 2. JAMA Netw Open. 2019 Feb 1;2(2):e188029. doi: 10.1001/jamanetworkopen.2018.8029. PubMed PMID: 30735236.

Ting DSW, Pasquale LR, Peng L, Campbell JP, Lee AY, et al. Artificial intelligence and deep learning in ophthalmology. Br J Ophthalmol. 2018 Oct 25; PubMed PMID: 30361278.

Lee A, Taylor P, Kalpathy-Cramer J, Tufail A. Reply: Machine Learning has arrived. Ophthalmology. 2018 Oct 18; PubMed PMID: 30343936.

Denniston AK, Lee AY, Lee CS, Crabb DP, Bailey C, et al. United Kingdom Diabetic Retinopathy Electronic Medical Record (UK DR EMR) Users Group: report 4, real-world data on the impact of deprivation on the presentation of diabetic eye disease at hospital services. Br J Ophthalmol. 2018 Sep 29;PubMed PMID: 30269098.

Lee AY, Lee CS, Pieters M, Maa AY, Cockerham G, et al. Differences in Tertiary Glaucoma Care in the Veterans Affairs Health Care System. JAMA Ophthalmol. 2018 Aug 16; PubMed PMID: 30128546.

Lee CS, Larson EB, Gibbons LE, **Lee AY**, McCurry SM, et al. Associations between recent and established ophthalmic conditions and risk of Alzheimer's disease. Alzheimers Dement. 2018 Aug 2;PubMed PMID: 30098888.

Lee CS, Lee AY, Akileswaran L, Stroman D, Najafi-Tagol K, Kleiboeker S, Chodosh J, Magaret A, Wald A, Van Gelder RN; BAYnovation Study Group. Determinants of Outcomes of Adenoviral Keratoconjunctivitis. Ophthalmology. 2018 Mar 27. pii: S0161-6420(17)32895-6. PMID: 29602567

Mehta H, Tufail A, Daien V, Lee AY, Nguyen V, et al. Real-world outcomes in patients with neovascular agerelated macular degeneration treated with intravitreal vascular endothelial growth factor inhibitors. Prog Retin Eye Res. 2018 Jan 2; PubMed PMID: 29305324.

Lee AY, Butt T, Chew E, Agron E, Clemons TE, Egan CA, Lee CS, Tufail A; UK EMR AMD Research Group. Cost-effectiveness of age-related macular degeneration study supplements in the UK: combined trial and real-world outcomes data. Br J Ophthalmol. 2018 Apr;102(4):465-472. PMID: 28835423

Xiao S, Bucher F, Wu Y, Rokem A, Lee CS, Lee AY. Fully automated, deep learning segmentation of oxygen-induced retinopathy images. JCI Insight. 2017 Dec 21;2(24)PubMed PMID: 29263301

Lee A, Taylor P, Kalpathy-Cramer J, Tufail A. Machine Learning Has Arrived!. Ophthalmology. 2017 Dec;124(12):1726-1728. PubMed PMID: 29157423.

Lee AY, Lee CS, Egan CA, Bailey C, Johnston RL, et al. UK AMD/DR EMR REPORT IX: comparative effectiveness of predominantly as needed (PRN) ranibizumab versus continuous aflibercept in UK clinical practice. Br J Ophthalmol. 2017 Dec;101(12):1683-1688. PubMed PMID: 28478396; NIHMSID: NIHMS906276; PubMed Central PMCID: PMC5673590.

Denniston AK, Chakravarthy U, Zhu H, Lee AY, Crabb DP, et al. The UK Diabetic Retinopathy Electronic Medical Record (UK DR EMR) Users Group, Report 2: real-world data for the impact of cataract surgery on diabetic macular oedema. Br J Ophthalmol. 2017 Dec;101(12):1673-1678. PubMed PMID: 28487377. Lee AY, Butt T, Chew E, Agron E, Clemons TE, et al. Cost-effectiveness of age-related macular degeneration study supplements in the UK: combined trial and real-world outcomes data. Br J Ophthalmol. 2017 Aug 23;PubMed PMID: 28835423.

Lee CS, Van Gelder RN, Lee AY. Reply. Ophthalmology. 2017 Aug;124(8):e65-e66. PubMed PMID: 28734343.

Lee CS, Lee AY, Baughman D, Sim D, Akelere T, et al. The United Kingdom Diabetic Retinopathy Electronic Medical Record Users Group: Report 3: Baseline Retinopathy and Clinical Features Predict Progression of Diabetic Retinopathy. Am J Ophthalmol. 2017 Aug;180:64-71. PubMed PMID: 28572062. *Corresponding author

Lee CS, Tyring AJ, Deruyter NP, Wu Y, Rokem A, Lee AY. Deep-learning based, automated segmentation of macular edema in optical coherence tomography. Biomed Opt Express. 2017 Jul 1;8(7):3440-3448. PubMed PMID: 28717579; PubMed Central PMCID: PMC5508840.

Lee CS, Boughman DM, Lee AY. Deep learning is effective for the classification of OCT images of normal versus Age-related Macular Degeneration. Ophthlamology Retina. 2017. In press.

Lee CS, Su GL, Baughman DM, Wu Y, **Lee AY**. Disparities in delivery of ophthalmic care; An exploration of public Medicare data. PLoS One. 2017;12(8):e0182598. PubMed PMID: 28787015; PubMed Central PMCID: PMC5546578.

Lee CS, Kim AJ, Baughman D, Egan C, Bailey C, Johnston RL, Natha S, Khan R, Brand C, Akerele T, McKibbin M, Downey L, Al-Husainy S, Lee AY*, Tufail A. VISUAL ACUITY IMPROVEMENT WHEN SWITCHING FROM RANIBIZUMAB TO AFLIBERCEPT IS NOT SUSTAINED. Retina. 2017 Apr 11. * Co last author

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Book chapters

None

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DATA MANAGEMENT PLAN

Any Applicants, contractors, or agents receiving CHIA data that includes Protected Health Information ("PHI" as defined under the Health Information and Portability Act [HIPAA] and its implementing regulations) as well as additional elements that may be used to identify an individual (the "Data") must complete and execute this Data Management Plan. The Data Management Plan(s) will be incorporated within the <u>Data Use Agreement</u> that must be executed prior to receipt of the Data. You may wish to refer to the Data Use Agreement as you complete this Data Management Plan. This Data Management Plan should be completed by the Chief Information Security Officer, Chief Privacy Officer, legal counsel or another officer of the organization with sufficient knowledge of the organization's data privacy and security practices and who has authority to bind the organization.

NOTE: This Data Management Plan is confidential and will not become a part of the public record.

I. GENERAL INFORMAITON

Retrospective Analysis of Ocular Data from the Massachusetts' Center for Health Information Analysis (CHIA) Database

II. CERTIFICATIONS

Applicant certifies and agrees as follows:

- The Data will be encrypted at rest encrypted on storage media (backup tapes, local hard drives, network storage, et al) with at least AES-256 standard or stronger.
- The Data will be encrypted in transit consistent with the approved method described in this Data Management plan at section IV.3-b.
- Anti-virus software or service is active on any server or endpoint containing the Data
- The Organization is in full compliance with the privacy and security requirements of HIPAA
- The Organization has policies and procedures in place to address:
 - The sharing, transmission and distribution of PHI
 - The physical removal, transport and transmission of PHI
 - o The physical possession and storage of PHI
 - o The training of all staff who will access PHI on the requirements of HIPPA
 - The destruction of PHI upon the completion of its use.
 - o Confidentiality agreements will all individuals, including contractors, who will access PHI
 - o Business Associate Agreements with all non- employees who will access PHI

III. RESPONSIBLE PARTIES

Please identify the following individuals within your organization:

1. The individual responsible for organizing, storing and archiving the Data. This individual is the Custodian of the CHIA Data required under Section 20 of the Data Use Agreement.

Name:	Cecilia Lee, MD
Title:	Assistant Professor
Phone:	206-685-4705
Address:	HMC Box 359608, 325 9 th Ave, Seattle, WA 98104
Email:	Leecs2@uw.edu
Reports to (name and title):	Russell Van Gelder, MD, PhD. Professor and Chair of the University of Washington Medicine Department of ophthalmology.

2. The individual(s) responsible for the research team using the Data, including ensuring each individual (i) has a signed confidentiality agreement, (ii) accesses and uses only the minimal Data necessary to achieve the research purpose, (iii) accesses the Data only on a secured server according to Applicant's policies. This individual is also responsible for maintaining the access log required under Section 5 of the Data Use Agreement.

Name:	Cecilia Lee, MD
Title:	Assistant Professor
Phone:	206-685-4705
Address:	HMC Box 359608, 325 9 th Ave, Seattle, WA 98104
Email:	Leecs2@uw.edu
Reports to (name and title):	Russell Van Gelder, MD, Phd. Professor and Chair of the University of Washington Medicine Department of ophthalmology.

3. The individual responsible for notifying CHIA of any breach of the Data Use Agreement or this Data Management Plan.

Name:	Cecilia Lee, MD	·
Title:	Assistant Professor	
Phone:	206-685-4705	

Address:	HMC Box 359608, 325 9 th Ave, Seattle, WA 98104
Email:	Leecs2@uw.edu
Reports to (name and title):	Russell Van Gelder, MD, Phd. Professor and Chair of the University of Washington Medicine Department of ophthalmology.

4. The individual responsible for ensuring the Data is destroyed upon termination of the Data Use Agreement, completing the Data Destruction Form and providing that Form to CHIA.

Name:	Cecilia Lee, MD
Title:	Assistant Professor
Phone:	206-685-4705
Address:	HMC Box 359608, 325 9 th Ave, Seattle, WA 98104
Email:	Leecs2@uw.edu
Reports to (name and title):	Russell Van Gelder, MD, Phd. Professor and Chair of the University of Washington Medicine Department of ophthalmology.

IV. DATA SECURITY AND INTEGRITY

Complete this section for each location where the Data will be stored or accessed. If you plan to use an agent/contractor that has access to the Data at a location other than your location or in an off-site server and/or database, the agent/contractor must also complete this section.

1. Physical Location of the Data:

a. Please provide the delivery address for the Data, as well as the full address, including building and floor, of each location where Data will be stored.

Organization: University of Washington, Medicine, De	partment of Ophtha	lmology	
Street Address: 908 Jefferson St, 8 th floor	City: Seattle	State: WA	ZIP Code: 98104
Office Telephone (Include Area Code): 206-543-7250			

If the storage location above is managed by a third party then answer the following:

	i.	Will the Data be stored by the third party on a system in the cloud (reachable via the Internet)? \square Yes \square No
	ii.	If you answered yes to (a): Has this Cloud Service Provider passed a FedRAMP 3PAO assessment for the specific cloud system which will host the data?
	iii.	\square Yes \square No If you answered yes to (b): What is the name of the provider <i>and</i> the FedRAMP level the specific cloud system hosting the data is operating at?
	,	
2.	<u>Data P</u>	rivacy Training and Awareness:
	a.	Has every individual who will access the data received training on the proper handling of protected health information and/or personal data within the last year? ☑ Yes □ No
3.	<u>Encryp</u>	tion of Data:
	a.	Will all CHIA Data at rest be encrypted on storage media (backup tapes, local hard drives, network storage, et al) with encryption at least AES-256 or stronger. ☑ Yes □ No
	b.	Will CHIA Data transmitted by your organization over the Internet? ☐ Yes ☑ No
		If you answered yes to (b): which of the following if any are used when transmitting data over the internet? If selecting other please describe method in space provided below.
		☐ SSL (meets or exceeds TSL 1.1 or TSL 1.2) ☐ SFTP ☐ Other
 4.	Inform	ation Security:
	a.	Does your organization have published information security policies which are followed and accessible to all staff accessing or handling CHIA Data? Staff accessing or handling CHIA Data?
		Has every individual who will access the CHIA Data received cyber security awareness training in the last year? ⊠ Yes □ No
	c.	Has your IT organization experienced a breach of PHI or PII in the last seven (7) years? ☑ Yes □ No

If you answered yes to (c): how was the breach resolved?

Although no data was confirmed to be breached, we chose to notify the patients and alterted HHS to the incident. We wiped the computer and have implemented many controls to help mitigate further incidents. We also have hired a CISO and added 6 additional security members to the team. We have implemented a risk management based information security program and are reporting risks, risk mitigation plans, assets, etc to the executive committee on a monthly basis.

5.	. <u>Technical and Physical Controls:</u>			
	a,	Are all the user accounts that log on to any machine (server or endpoint) that accesses the		
		uniquely assigned to individual users (i.e., the user accounts are not shared)?		

⊠ Yes □ No

b.	Is an audit log maintained of all user log-ons to the system hosting the CHIA Data?

c. What is the minimum password length and character complexity (uppercase, lowercase, numeric, and special characters) required for new passwords on the user accounts logging on to the system accessing the CHIA Data?

- Be between 8 and 13 characters long.
- Include at least one upper case letter (A-Z)
- Include at least one lower case letter (a-z)
- Include at least one numeric digit (0-9)
- Include at least one of the following symbols:
- `!@#\$%^&*()-_+={}[]:<>.?/

d. Describe any additional authentication technical security controls you employ to defend the system against unauthorized logon, e.g. maximum failed login attempts, lockout period, etc.:

UW Medicine Passwords must be updated every 120 days and meet the minimum requirements as outlined above in section 5.c.

e. Do you'run a current version of a commercial off-the-shelf anti-virus or anti-malware product on the server that will host the CHIA Data?

Data

		⊠ Yes □ No
	f.	If the CHIA Data will be on a server or network accessible storage drive, then check all the security
•		features present in the room containing CHIA Data:
		i. 🗌 Recorded video
		ii. 🗵 Access log of all individuals entering the room
		iii. 🛮 Secure server rack
		iv. 🛮 Access control limiting access only to authorized individuals
	g.	What additional specific physical or technical safeguards (not mentioned in prior answers) will be used
· ·		to mitigate the risk of unauthorized access to CHIA Data?
		ated in one of our UW Medicine secured data centers and has the overall physical, technical, and
administra	tive	controls required to ensure no unauthorized access, use, or disclosure of the data.
<u> </u>		
	h	When was the last information security risk assessment performed in your organization? Who
	•••	conducted it?
We have in	nple	mented an ongoing risk assessment process that looks at risk across the entire enterprise throughout the
		re reviewed by our CISO security team, internal audit, compliance teams, and external auditors. Reports
('		essments are reported to our executive security committee on a monthly basis.
	1	When was the last IT audit performed in your organization? Who conducted it?
	i.	when was the last it addit performed in your organizations. Who conducted its
All of the a	hove	e mentioned teams have assessed UW Medicine within the last year.
Allorulea	DOVE	. mentioned teams have assessed our meations maint are tast year.
V. DA	TA R	ETURN OR DESTRUCTION

Applicants are required to attest that the CHIA Data and all copies of the CHIA Data used by the Applicant or its employees, contractors or agents will be destroyed by the Retention Date as specified in the Data Use Agreement, or upon completion of the project described in your Application, whichever occurs first. All data destruction must conform to the requirements of M.G.L. c. 931 and to the Data Use Agreement. Please specify below the technical measures you will use to meet these requirements.

Upon completion of the research, the CISO will meet with the research team to review the data location and certify the logical destruction of the data and removal of the share (if applicable). If physical hard drives need to be destroyed, the

destruction will follow our normal destruction and logging process through IT services.

VI. SIGNATORY

The undersigned is an authorized signatory of the organization. The organization hereby agrees to hold and/or access CHIA Data at all times in compliance with all provisions of this Data Management Plan.

Name:	Russell Van Gelder, MD, PhD
Title:	Professor and Chair
Organization:	University of Washington Medicine Department of ophthalmology
Signature:	Aust Rule
Date:	9/29/16 7/11/19